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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/418,176

Applicant(s)

Das, G.

Examiner

Peter Tung

Art Unit

1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 15, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, and 15 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 08/624,398.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Claims 1-12, 14 and 15 are pending.

#### *Double Patenting*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-12, 14 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9, 10, 12 and 14 of U.S. Patent No. 5,827,683 in view of Martinez et al. This rejection is explained in the previous Office action. The instant SEQ ID NO: 3 is identical to SEQ ID NO: 3 of U.S. Patent No. 5,827,683.

4. Applicants argue that although a number of signal peptides and yeast expression systems were known at the time of filing of the instant application, it would not have been predictable which ones would allow correct and efficient high level expression of the active polypeptide. Applicants argue that there is unpredictability known to exist in the field at the time of the instant invention such that one of skill would not have been automatically motivated to use the teachings

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of Martinez et al. Applicants argue that *S. cerevisiae* was tried as host for the expression of BSSL and that this expression system was ineffective. Applicants argue that, accordingly, the use of *S. cerevisiae* would also have been obvious at the time of the instant invention. Therefore, success in *P. pastoris* expression would not have been prima facie obvious, i.e. expected.

5. Applicant's arguments filed 6/15/01 have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon what would not have been predictable which expression system would allow correct and efficient high level expression of the active polypeptide, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, i.e., the claimed subject matter. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With regard to success being expected, Applicant's lack of success with the use of *S. cerevisiae* is insufficient to lead one of ordinary skill in the art to expect that BSSL expression in *P. pastoris* will not work.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 4-12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al. (U.S. Patent No. 5,200,183) in view of Stroman et al. (U.S. Patent No. 4,808,537). This rejection is explained in the previous Office action. The instant SEQ ID NO: 3 is identical to SEQ ID NO: 3 of Tang et al.
8. Claims 3 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al. (U.S. Patent No. 5,200,183) in view of Martinez et al. This rejection is explained in the previous Office action.
9. Applicants argue that the mere throwing together of different disclosures and the assertion that it would have been obvious at the time to do so, do not stand up to the unpredictability in the art and the equally significant discouraging results known to those working in the field. Applicant further argues that the Tang et al. reference was also cited during prosecution of the application from which Patent No. 5,827,683 issued and which the Examiner in that application ultimately acknowledged the patentable distinctness of that application over Tang et al.
10. Applicant's arguments filed 6/15/01 have been fully considered but they are not persuasive. As stated in the previous Office action, it would have been obvious to do so for the benefit of having an expression vector for high level expression of BSSL in *Pichia pastoris* and that one of ordinary skill in the art is motivated to combine the two teachings as Tang et al. teach expression of the lipase in yeast and Stroman et al. teach expression vectors for *Pichia pastoris* expression.

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There is no substantial evidence provided by Applicant that the unpredictability in the art and the equally significant discouraging results known to those working in the field is such that one of ordinary skill in the art would not have even considered combining the teachings cited.

As each application is considered on its own merits, whether or not the Tang et al. reference is pertinent to the instant application is based on the reference's relevance to the instant application and not on its relevance to another application.

### *Conclusion*

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



PONNATHAPU ACHUTAMURTHY  
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09 418,176	10 13 1999	GOUTAM DAS	1103326-0206	8505

7470 7590 10 09 2002  
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NEW YORK, NY 10036

EXAMINER

RAMIREZ, DELIA M

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